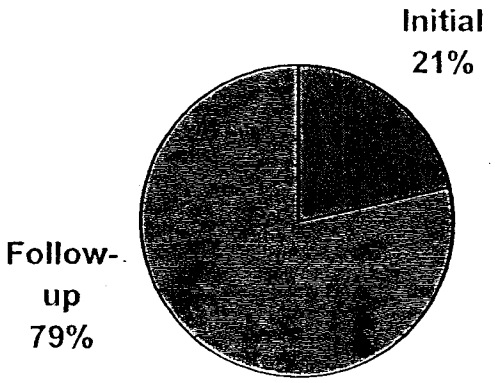
QSIT

Study

QSIT STUDY INSPECTIONS

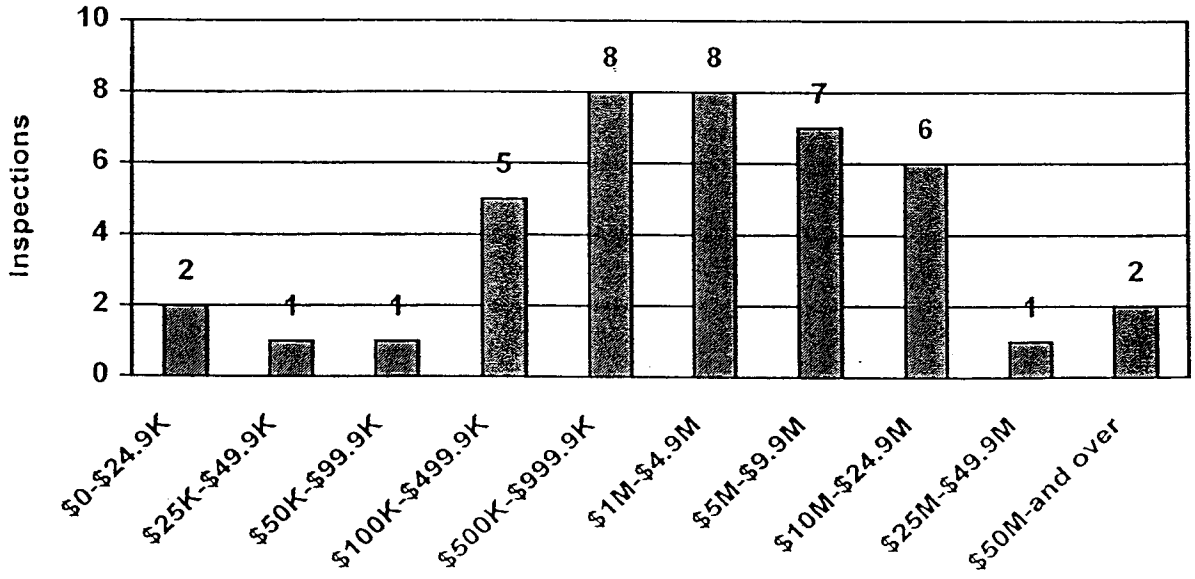
The QSIT Study was conducted 10/1/98 through 2/19/99. During the Study period 12 QSIT trained investigators, 4 each from DEN-DO, LOS-DO, and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study.

Of the 42 inspections, 9 were initial inspections of the firm's operations. The remaining 33 were follow-ups to a previous inspection.



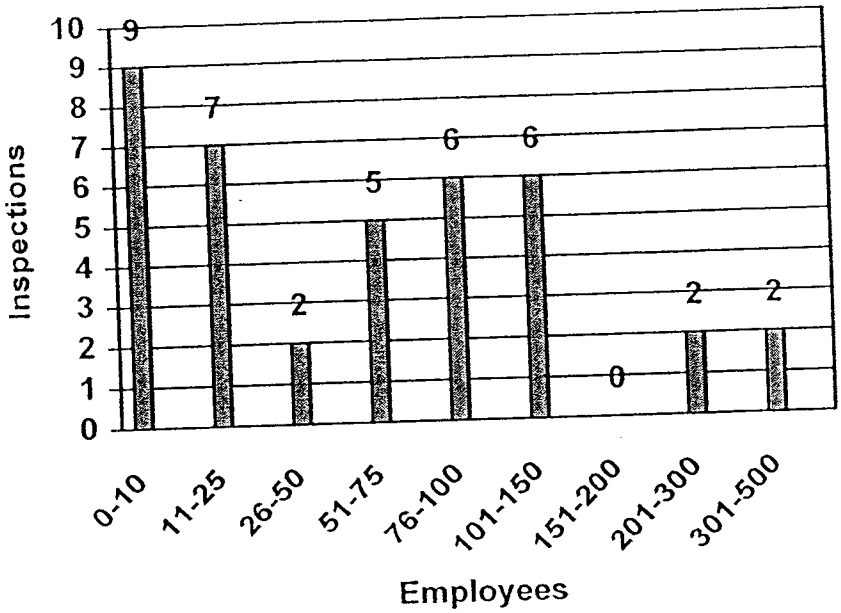
Types of Inspections

The annual dollar volumes as reported for 41 of the 42 inspected firms are as follows:

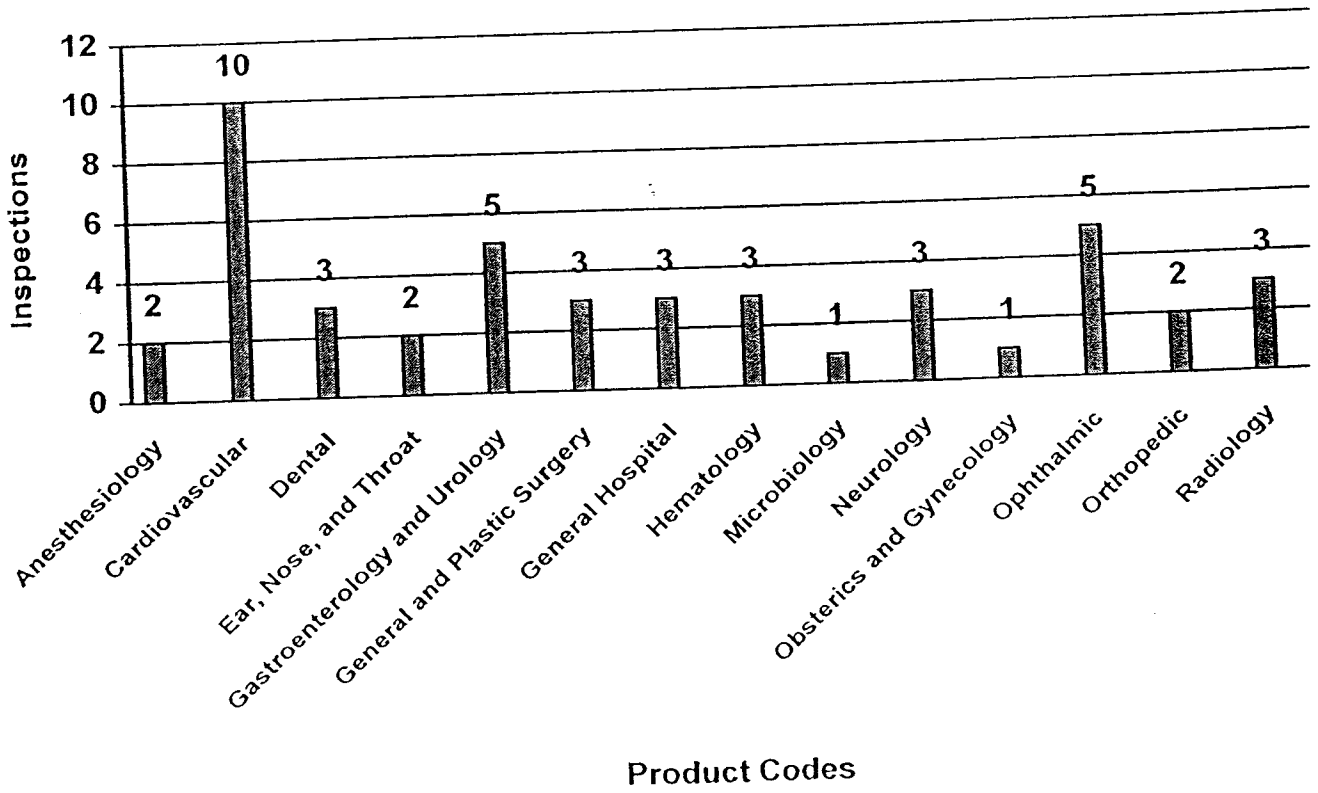


Annual Dollar Volumes

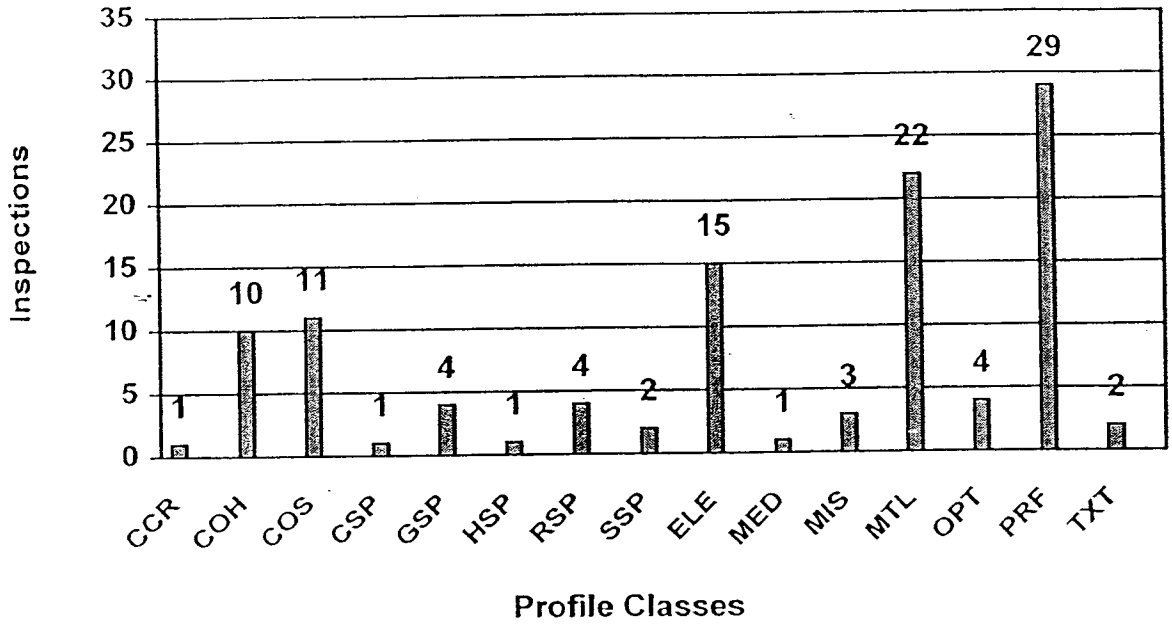
The approximate numbers of employees as reported for 39 of the 42 firms are shown below.



The product codes associated with those 42 inspections are shown below. *Note - For some inspections more then one product code was covered.*



The profile classes covered during those 42 inspections are as follows:



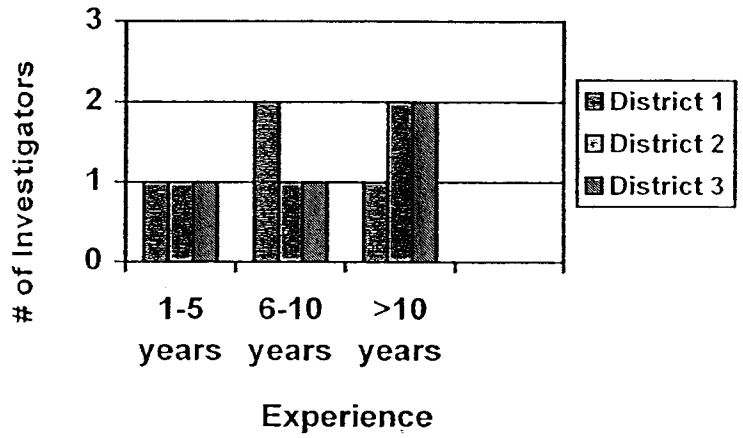
PROFILE CLASS CODES AND DEFINITIONS

CCR	Clinical Chemistry Reagents
COH	Computer Hardware
COS	Computer Software
CSP	Chemical Sterilization
GSP	Gas Sterilization
HSP	Dry Heat Sterilization
RSP	Radiation Sterilization
SSP	Steam Sterilization
ELE	Electrical Assembly
MED	Media
MIS	Not Elsewhere Classified
MTL	Metals Fabrication and Assembly
OPT	Optics Fabrication and Assembly
PRF	Plastic or Rubber Fabrication and Assembly
TXT	Textile Fabrication and Assembly

The following attached Forms were developed to collect and document the Study data associated with various validation activities:

1. QSIT Review (FDA 481(a), (c) and EIR) (Rev. 1/11/99)
2. QSIT FDA 483 Focus Review (Rev. 1/12/99)
3. INVESTIGATOR QSIT EVALUATION FORM (Rev. 9/30/98)
4. COMPLIANCE OFFICER QSIT EVALUATION FORM (Rev. 9/30/98)
5. Cover letter for QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY
6. QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY

The experience levels of the investigators performing the 42 QSIT Study inspections are shown below:



QSIT Review
(FDA 481(A), (C), and EIR)

District: DEN LOS MIN

Firm Name: _____

EI TYPE: INITIAL FOLLOW-UP EST TYPE: _____ EST SIZE: _____

PAC	PROCESS CODE	HOURS	PRODUCT	INSP CONC	DIST CONC

FDA 483 ISSUED: YES NO

PROFILE CLASS(es): _____ _____ _____ _____ _____ _____ _____

QSIT EIR ELEMENTS:

Design Project Covered: _____

Data Sources reviewed during evaluation of the CAPA subsystem: _____

_____

Process(es) covered: _____

COMMENTS: _____

_____

_____

Reviewer: _____ Date: _____

QSIT FDA 483 Focus Review

District: DEN LOS MIN

Firm Name: _____

FDA 483 observations were identified from the following subsystems and correspond to the following steps in the flowcharts in the QSIT Handbook:

Management:	1	2	3a	3b	4a	4b	5	6		
Design Ctrls:	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15					
CAPA:	1	2	3	4	5	6	7	8	9	10
P&PC:	1a	1b	2	3a	3b	4	5	6		

Other subsystems (identify cite) –

Doc/Records & Ch. Ctrls:

Facilities & Equip. Ctrls:

Material Ctrls:

Comments:

Reviewer: _____ Date: _____

INVESTIGATOR QSIT EVALUATION FORM

Firm Name _____ Inspection Date(s)_____
CFN _____

Approximate number of employees in firm _____

SUBSYSTEMS COVERED		APPROXIMATE TIME IN-PLANT
Management Controls	_____	_____
Design Controls	_____	_____
CAPA	_____	_____
PAPC *	_____	_____

*(Number of processes covered _____)

1. Was the inspection pre-announced? Yes _____ No _____
   If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes _____No_____
   If yes, were the records reviewed? Yes _____ No _____
   If yes, how much time was expended to review those records? _____
   Did this review increase the efficiency of the inspection? Yes _____ No _____
   Comments _____
   _____

2. Were the QSIT tools (Handbook - Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during this inspection? Yes _____ No _____
   If yes, which tools were most useful and how were they helpful? _____
   _____
   _____

3. Did use of the QSIT result in a more focused inspection? Yes _____ No _____
   Comments _____
   _____

4. Did use of the QSIT result in a more efficient inspection? Yes _____ No _____
   Comments _____
   _____

5. Other Comments: _____
   _____

Investigator: _____ Date: _____

Please submit this completed form to: Tim Wells, QSIT Team Leader, FDA CDRH HFZ-332, 2098 Gaither Rd., Rockville, MD 20850 .

(Rev date 9/30/98)

COMPLIANCE OFFICER QSIT EVALUATION FORM

Firm Name _____ Inspection Date (s) _____
CFN _____

BY USING THE QSIT STUDY PART V:

1. What classification would you make? _____

2. If classified OAI, which QSIT Study Part V requirements were met?
   A _____ B _____ C _____ D _____ E _____

3. Did the QSIT Study Part V help you in making your decision? Yes _____ No _____
   Comments _____
   _____

4. Did the QSIT Study Part V make your decision process more complicated? Yes____No____
   Comments_____
   _____

5. Did you find the QSIT Study Part V too structured? Yes _____ No _____
   If yes, explain._____
   _____

6. Did the investigator's focus on key areas help make your review easier? Yes _____ No _____
   Comments _____
   _____

7. Were the QSIT tools (Handbook - Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) useful during your review? Yes _____ No _____
   If yes, which tools were most useful and how were they helpful? _____
   _____
   _____

8. Other Comments: _____
   _____

Compliance Officer: _____ Date: _____

Please submit this completed form and a copy of the EIR, FDA483, if issued, CGCS with PDS, and WL, if issued, to: Tim Wells, QSIT Team Leader, FDA CDRH HFZ-332, 2098 Gaither Rd., Rockville, MD 20850

(Rev date 9/30/98)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

The Center for Devices and Radiological Health is currently engaged in a reengineering effort to improve our Quality System/Good Manufacturing Practice inspection program. The goals of this reengineering effort are to conduct more focused and efficient inspections using an inspection technique called the QSIT (Quality System Inspection Technique) that is closer aligned with that inspection technique used by the international community. We believe these goals would benefit both the FDA and the industry.

The QSIT is being studied in several FDA Districts. The inspection of your facility, on the above dates, was conducted using this technique.

As part of our evaluation of that study, we would like your views on the QSIT. We are requesting that you provide those views by completing the enclosed survey form. Participation in this survey is voluntary. However, we do hope you will respond because we believe your views will provide valuable input into our reengineering effort.

Please submit the completed survey form by mail or fax to: Ms. Georgia Layloff, QSIT Team, FDA, 12 Sunnen Drive, Suite 122, St. Louis, MO 63143, FAX 314-645-2969, Phone 314-645-1167, ext. 121, email glayloff@ora.fda.gov.

If you have any questions, please contact Georgia Layloff or myself.

Thank you in advance for your assistance.

Sincerely yours,

Timothy Wells
QSIT Team Leader
Center for Devices and Radiological Health
301-594-4616, ext. 126

Enclosure: As stated

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT)
CUSTOMER SATISFACTION SURVEY

Please provide the following information:

1. Did your company receive advance notification of the inspection? Yes [ ] No [ ]
   If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ]
   If yes, which records were voluntarily provided? _____
   _____
   Did providing such records facilitate the inspection process? Yes [ ] No [ ]
   Please explain. _____
   _____
   _____

2. Did the QSIT focus on the key elements of your quality system? Yes [ ] No [ ]
   If yes, how did this focus prove beneficial to your firm? Please give examples.
   _____
   _____
   _____

3. Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ]
   If yes, how did this efficiency prove beneficial to your firm? Please give examples.
   _____
   _____
   _____

4. We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No Opinion or Experience with this subject [ ]
   If yes, was this useful to your firm? Yes [ ] No [ ]
   Explain and provide examples of the similarities and usefulness. _____
   _____
   _____
   _____

5. Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ]
   Please explain. _____
   _____
   _____

6. Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ]
   Please explain. _____
   _____
   _____

7. Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ]
   Please explain. _____

8. Do you think that use of the QSIT will increase FDA's effectiveness in protecting and promoting the public health? Yes [ ] No [ ]
   Please explain. _____

9. How would you improve the QSIT?

10. Comments _____

Optional Items: Please note, the following information is not required to participate in the survey. The information may be used in the event we have follow-up questions.

Contact Name: _____
Firm Name: _____
Address: _____

Telephone Number: _____ *Fax Number:* _____
email Address: _____

Thank you for completing this survey. Your responses are very important to us. They will be used to assist in improving our efforts.

Please send this completed form by mail or fax to: Georgia Layloff, QSIT Team, FDA, 12 Sunnen Drive, Suite 122, St. Louis, MO 63143, fax (314) 645-2969.